

Remarks

1.0 35 U.S.C. 112, second paragraph

The Office Action rejected claim 8 under 35 U.S.C. 112, second paragraph, as indefinite. This amendment overcomes that objection by amending claim 8 to remove the language "other positively charged functional groups".

2.0 35 U.S.C. 102 – Novelty

The Office Action rejected claims 1-18 as lacking novelty over U.S. Patent 5,965,631 to Nicolson et al. ("Nicolson"). Applicants respectfully traverse and request reconsideration.

(5) Nicolson discloses the use of poly(ethylene glycol) as a reactant in one step of a synthetic process for making a polysiloxane macromer (column 19, lines 30-57). In contrast, applicants claim a method for inhibiting the ability of a biomaterial to sorb cationic antimicrobials. The claimed method requires treating the surface of the biomaterial with a cationic polysaccharide. Please see claim 1.

The Nicholson method for synthesizing a polysiloxane macromer cannot anticipate the claimed method for treating the surface of a biomaterial. Applicants request that the rejection under 35 U.S.C. 102 be reconsidered and withdrawn.

3.0 35 U.S.C. 103 - Unobviousness

The Office Action rejected claim 19 under 35 U.S.C. 103(a) as obvious over Nicolson taken in view of U.S. Patent 4,992,536 to Billmers et al. ("Billmers").

Billmers teaches a method for making polysaccharides that are said to be especially useful in the manufacture of paper. Please see the abstract.

(6) The applicants' claim 19 depends from claim 1 and therefore incorporates all the limitations of claim 1. As discussed above, Nicholson discloses the use of poly(ethylene glycol) as a reactant in one step of a synthetic process for making a polysiloxane macromer (column 19, lines 30-57). One of ordinary skill could then look to Billmers for a variety of polysaccharides. But these two references together lack what is needed for a proper finding of *prima facie* obviousness against the applicants' claims. The combined references do address the subject matter of the applicants' claimed invention: they fail to even recognize that the sorption of antimicrobials by biomaterials is a problem that needs to be solved.

The cited references lack three elements that are required for a proper finding of *prima facie* obviousness.

- (a) No cited reference recognizes that antimicrobial sorption is a problem that needs to be solved. Thus no cited reference can provide any suggestion or motivation to treat the surface of a biomaterial as claimed to inhibit its ability to sorb antimicrobials.
- (b) Failing to address the problem of antimicrobial sorption, no reference provides any reasonable expectation that the claimed process might work. Only the applicants' provides the necessary expectation of success.
- (c) The combined references fail to teach all of the limitations of the applicants' claims. Specifically, the cited patents fail to teach a method for treating the surface of a biomaterial using a cationic polysaccharide.

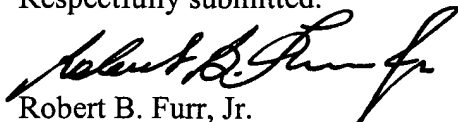
For these reasons, the cited patents cannot support a finding of *prima facie* obviousness. Please see MPEP 2142 at page 2100-97, column 1. A copy of that page is enclosed for convenient reference.

Applicants request that the rejection under 35 U.S.C. 103(a) be reconsidered and withdrawn.

4.0 Conclusion

If any other matters require resolution before issuing the Notice of Allowance, the examiner is invited to telephone the undersigned attorney. Notice of Allowance is hereby requested.

Respectfully submitted.



Robert B. Furr, Jr.
Registration No. 32,985
Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, New York 14604-2701
Telephone: (716) 338-6530

Dated: June 11, 2001
Furr/ptopres/2389R1.doc

VERSION WITH MARKINGS TO SHOW CHANGES MADE

8. (once amended) The method of claim 6 wherein the cationic charge on the cationic polysaccharide is derived at least one selected from the group consisting of ~~from~~ ammonium groups, quaternary ammonium groups, sulfonium groups, and phosphonium groups, ~~and other positively charged functional groups.~~

NOT AVAILABLE



aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP § 2144 - § 2144.09 for examples of reasoning supporting obviousness rejections.

When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). A statement of a rejection that includes a large number of rejections must explain with reasonable specificity at least one rejection, otherwise the examiner procedurally fails to establish a *prima facie* case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Rejection based on nine references which included at least 40 prior art rejections without explaining any one rejection with reasonable specificity was reversed as procedurally failing to establish a *prima facie* case of obviousness.).

If the examiner determines there is factual support for rejecting the claimed invention under 35 U.S.C. 103, the examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

When an applicant submits evidence, whether in the specification as originally filed or in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a discussion of the proper roles of the examiner's *prima facie* case and applicant's rebuttal evidence in the final determination of obviousness. See MPEP § 706.02(j) for a discussion of the proper contents of a rejection under 35 U.S.C. 103.

2143 Basic Requirements of a *Prima Facie* Case of Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).